PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NO 7479/WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/006469	International filing date *(day/month/year)* 16.06.2004	Priority date *(day/month/year)* 23.06.2003
International Patent Classification (IPC) or national classification and IPC A23L1/305, A23L1/29, A23K1/16, A23K1/18, A61K38/00, A61K31/195		
Applicant NESTEC S.A.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19.01.2005	10.08.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Couzy, F Telephone No. +49 89 2399-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/006469

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-12	as originally filed
Claims, Numbers	
1-14	as originally filed
Drawings, Sheets	
1	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 12-14 (IA)

because:

☒ the said international application, or the said claims Nos. 12-14 (IA) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 12-14 (IA)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6, 8-25
	No:	Claims	1-14
Inventive step (IS)	Yes:	Claims	1-6, 8-21, 24-25
	No:	Claims	1-14
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 Claims 12-14 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. **Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims** (Article 34(4)(a)(I) PCT). In fact, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 Reference is made to the following documents:

D1: EP-A-1 281 325 (NESTLE SA) 5 February 2003
D2: US 2001/031723 A1 (BALLEVRE OLIVIER ET AL) 18 October 2001
D3: WO 99/14231 A (ZUCHT HANS DIETER ;LIEPKE CORNELIA (DE); FORSSMANN WOLF GEORG (DE)) 25 March 1999
D4: GB-A-1 159 615 (VIVONEX CORPORATION) 30 July 1969
D5: DE 100 24 746 A (IH BRT N V) 22 November 2001
D6: WO 00/22945 A (SCHIFFRIN EDUARDO; DONNET ANNE (CH); NESTLE SA (CH); VIDAL KARINE) 27 April 2000
D7: US 2003/008016 A1 (ZIVKOVIC D DOROTHEA ET AL) 9 January 2003
D8: US-A-5 322 836 (SHIMAMURA SEIICHI ET AL) 21 June 1994
D9: US-A-5 531 988 (PAUL STEPHEN M) 2 July 1996
D10: WO 01/58283 A (FRIESLAND BRANDS BV ;LEEUWEN PAULUS ALUISIUS MARIE (NL); GLAS CORN) 16 August 2001
D11: US-B-6 180 0991 (PAUL STEPHEN M) 30 January 2001
D12: DATABASE WPI Week 2002 Derwent Publications Ltd., London, GB; AN 2002-436267 XP002300655 CHEN Y, HAO Y, KONG F: "Health oral liquid" & CN 1 181 244

A (KONGYUAN BIOLOGICAL HEALTH GEN PLANT HUB) 13 May 1998

V.2 **Novelty and inventive step**

Abundant prior art describes compositions comprising amino acids, either as such or as peptides or proteins, for the regulation of the gut flora and/or of bacterial translocation and/or of gut immunity and/or for the prevention of allergies. It is also noted that in claims 5 and 11, where amounts of amino acids are specified, these are regrettably specified in terms of daily dosages to be administered, and not of the amount which is indeed present in the composition. That unclarity (Art. 6 PCT) results in the fact that these amounts can not be used to characterize the compositions themselves. A further general point to note is that since therapeutic compositions comprising amino acids according to claims 1 and 2 are known (e.g., see below), and since the concentrations of the amino acids are not clearly defined, it appears unlikely that the applicant will be able to establish novelty of the compositions, at least under the European Patent Convention. And a last general point is that, should the applicant decide to restrict the scope of the claims, unity might become an issue.

More specifically, the subject-matter of claims 1-14 is not new over D1 (the amino acid composition of whey protein is known, and it includes the amino acids specified in e.g., claim 2), that of claims 1-6 not new over D2, that of claims 1-6 and 12 over D3, of claims 1-5 over D4, of claims 6, 12, and 14 over D5, of claims 6, 8, 10, 12-14 over D6, of claims 6, 12 and 14 over D7, of claim 6 over D8, of claim over D9, of claims 7, 13-14 over D10, of claims 6 and 12 over D11, and of claim 14 over D12 (Art. 33 (2) PCT).

V.3 The subject-matter of claims 1-11 is industrially applicable in the sense of Art. 33 (4) PCT.